(33)

No. 04-607

IN THE

Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS (doing business as LabCorp),

Petitioner,

v.

METABOLITE LABORATORIES, INC. and COMPETITIVE TECHNOLOGIES, INC.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

Respondents' brief is notable for what it does not contest. Respondents do not contest that, under the Federal Circuit's construction, every doctor who orders a homocysteine test and simply thinks about what the result might signify has infringed Claim 13. They do not contest that this holding has allowed them to monopolize *all* homocysteine testing, whether accomplished via methods existing before the Patent application, methods developed thereafter, or methods yet to be developed. And they do not contest that, if Claim 13 is valid, anyone who discovers a naturally occurring medical correlation could monopolize known and unknown testing methods by similarly drafting a vague "test plus correlate" claim.

Claim 13 involves nothing of any significance beyond the natural correlation it recites. As such, it violates both the proscription against patenting laws of nature or natural phenomena and the requirement under 35 U.S.C. § 112 that a valid claim recite and describe more than just a scientific principle. Respondents' attempts to defend their indefensible patent claim are refuted by the vast and ill-defined breadth of the claim – which recites *no* steps directing anyone to physically transform anything – and by this Court's precedents which hold that an artful draftsperson cannot render a patent valid merely by specifying a broad category of intended use.

The parties and amici have vigorously joined issue on all aspects of the question whether Claim 13 constitutes a prohibited monopoly over a basic scientific relationship rather than a patentable invention. That purely legal question is properly before the Court because it is included within the question on which certiorari was granted – over the same procedural objection respondents now belatedly raise. It is also a component of the Section 112 issues that are concededly before the Court, it was posed below, and it is an important question affecting the public interest that the Court has the inherent authority to consider. The Court should answer that question and reverse the judgment.

ARGUMENT

I. THE COURT CAN AND SHOULD ANSWER THE QUESTION PRESENTED.

There is no dispute that the Court has *jurisdiction* to consider whether Claim 13 seeks to patent a scientific principle. *See City of Canton* v. *Harris*, 489 U.S. 378, 383-384 (1989) ("respondent's contention that the claims made by petitioner here were not made in the same fashion below * * * does not affect our jurisdiction"). And there is no compelling prudential reason not to decide the legal issue on which certiorari was granted. The Court considered the petition carefully for a year, granted certiorari only after having been apprised in detail by the Solicitor General of the procedural objection respondents now belatedly raise, and limited the grant to the one question that LabCorp had made clear included subject matter patentability. As the Court has stated when presented at the merits stage with this kind of non-jurisdictional objection, "[i]n granting certiorari, [the Court] necessarily considered and rejected that contention as a basis for denying review." *United States* v. *Williams*, 504 U.S. 36, 40 (1992).

1. Now that certiorari has been granted, and there is no jurisdictional bar, the Court may consider any issue "fairly included" in the question presented. S. Ct. R. 14.1(a). Subject matter patentability is fairly included within the question presented, and should be decided for that reason alone. *See Vance* v. *Terrazas*, 444 U.S. 252, 258 n.5 (1980) (Court will consider issue necessary for an "intelligent resolution" of question presented); *Rumsfeld* v. *FAIR*, No. 04-1152, slip op. at 6 (U.S. 2006). The Court granted certiorari to decide, *inter alia*, whether Claim 13 "can validly claim a monopoly over a basic scientific relationship used in medical treatment." Pet. i. This "fairly include[s]" the question whether Claim 13 effectively seeks to patent a scientific principle. Not only is that the plain import of the words, but the petition repeatedly cited and relied on *Diamond* v. *Diehr*, 450 U.S. 175 (1981), and its predecessors, including in attacking validity. *See, e.g.*, Pet. 18, 19, 25-26, 27, 29; Pet. Reply 6. And even if

that were not sufficient to apprise the Court and the public of the precise contours of the question, LabCorp's supplemental brief before certiorari expressly stated that Question 3 of the petition *did* include the issue. *See* LabCorp Supp. Br. 5.[1]

Respondents are almost alone in professing not to understand that fact; even amici on their side agree that the question presented includes subject matter patentability. *See* Boston Patent Law Ass'n Br. 2; Perlegen Sciences Br. 3-25; Franklin Pierce Br. 2-30.[2] Respondents' argument that the petition only raised the issue to note a "consequence[ ]" of the Federal Circuit's decision, Resp. Br. 25, ignores reality. The petition stated that "[i]f the Federal Circuit decision is not corrected, CTI and others like it would improperly gain monopolies over basic scientific facts rather than any novel inventions of their own. * * * [T]his Court's precedents are settled that no such claim can be allowed." Pet. 25 (citing cases at Pet. 18). This was – almost verbatim – just what LabCorp had argued in the Federal Circuit. *See* Pet. Br. 14.

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[1] Given that the petition expressly relied on *Diehr* and other subject matter patentability cases, it was not necessary also to specifically cite 35 U.S.C. § 101 in order to present that issue. The Court's "jurisdiction does not depend on citation to book and verse." *Eddings* v. *Oklahoma*, 455 U.S. 104, 113 n.9 (1982). This Court's own invitation order cited *Diehr* but not § 101, yet the Solicitor General clearly understood the question the Court posed.

[2] Splitting hairs, the Solicitor General argues that Question 3 includes only one patentability sub-theory – whether Claim 13 preempts all substantial practical applications of the correlation. U.S. Br. 17. The question, however, asks whether the "patent * * * can validly claim a monopoly over a basic scientific relationship." Pet. i. Neither the question nor the petition is limited to any sub-theory. Tellingly, when the Court asked the Solicitor General in general terms whether Claim 13 is "invalid because one cannot patent 'laws of nature, natural phenomena, and abstract ideas,'" 125 S. Ct. 1413 (citation omitted), the Solicitor General did not limit his response to just one sub-theory. U.S. Cert. Br. 5-7, 11-15.

Respondents now belatedly object to this Court's consideration of the issue. But the very waiver principles on which they rely demonstrate that the Court can and should decide the question presented. Rule 15.2 of this Court "admonishe[s]" respondents "to point out in the brief in opposition and not later, any perceived misstatement made in the petition," and states that "[a]ny objection to consideration of a question presented *based on what occurred in the proceedings below*, if the objection does not go to jurisdiction, may be deemed waived unless called to the Court's attention in the brief in opposition." S. Ct. R. 15.2 (emphasis added). Respondents' brief in opposition failed to object in any way to consideration of subject matter patentability based on what occurred below or otherwise. And they continued to stand mute even *after* the Court specifically identified that issue and LabCorp's supplemental brief resolved any possible doubt that the issue was included within Question 3 – despite having had the same opportunity to file a supplemental brief.

The Court has held that "we do not think that judicial economy is served" by invoking a non-jurisdictional waiver objection "*after* we have granted certiorari and the case has received plenary consideration on the merits." *Oklahoma City v. Tuttle*, 471 U.S. 808, 815-816 (1985) (emphasis in original). That is because the "decision to grant certiorari represents a commitment of scarce judicial resources with a view to deciding the merits of one or more of the questions presented in the petition." *Id. Accord, City of Canton*, 489 U.S. at 384 ("because respondent did not oppose our grant of review at that time based on her contention that these claims were not pressed below, we will not dismiss the writ as improvidently granted"). So too here. The Court granted certiorari on an important legal question on which the parties and amici have fully joined issue. All that is left is to decide it.

2. The Court need go no further to conclude that it can and should decide the threshold issue of subject matter patentability. But the issue cannot be avoided for a further reason: it is a necessary component of the Section 112 questions that

all parties agree are properly before the Court.[3] It is conceded that the petition raises the question whether Claim 13 is invalid for insufficient enablement, disclosure, or description under Section 112, and that this question was expressly raised at all levels below. *See* Resp. Br. 13-18; Pet. App. 16a-18a. Respondents wrongly contend that this issue is "wholly separate" from whether Claim 13 seeks to patent a scientific principle. Resp. Br. 25 (emphasis deleted). In fact, this Court's landmark ruling in *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853), belies that assertion.

Morse originated the rule against patenting laws of nature or natural phenomena. *See* Pet. Br. 19. But the actual holding of *Morse* was that the claim at issue failed to meet the disclosure and enablement requirements currently set forth in 35 U.S.C. § 112.[4] The claim had sought to patent the use of a natural phenomenon – electromagnetism – for printing characters at a distance. The Court held that this claim violated the statutory requirements, now in Section 112, that a patentee "must deliver a written description of his invention or discovery, 'and of the manner and process of making,

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[3] The District Court understood this. In ruling on LabCorp's JMOL motion, the court stated that "whether you really can patent an idea * * * rather than a method" was "part of the argument." J.A. 174. LabCorp explained the same point to the Federal Circuit. *See* Pet. Br. 14. In any event, a party in this Court is not limited to the specific arguments made in support of a claim below. *See Yee v. City of Escondido*, 503 U.S. 519, 534 (1992).

[4] *See, e.g., LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (citing *Morse* for § 112 standard); *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 929 n.9 (Fed. Cir. 2004) (same); *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983) (*Morse* involved "what used to be known as 'undue breadth,' but has since been appreciated as being * * * based on the first paragraph of § 112"); *Application of De Castelet*, 562 F.2d 1236, 1242 (C.C.P.A. 1977) (*Morse* "principally involv[ed] an issue raisable today under § 112"); *cf. Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 257 (1928).

constructing, using, and compounding the same,' in such exact terms as to enable any person skilled in the art * * * to make, construct, compound, and use the same." 56 U.S. at 118 (quoting Patent Act of 1836, ch. 357, § 6, 5 Stat. 117).

As the Court held (*id.* at 119-120):

> [T]his claim can derive no aid from the specification filed. It is outside of it, and the patentee claims beyond it. And if it stands, it must stand simply on the ground that the broad terms abovementioned were a sufficient description, and entitled him to a patent in terms equally broad. In our judgment the act of Congress cannot be so construed.

The claim was thus invalid because Morse "claims what he has not described in the manner required by law." *Id.* at 120.

Just as Morse's claim was invalid under what is now Section 112 because it broadly claimed a natural phenomenon not limited to his actual telegraph invention, Claim 13 is likewise invalid under Section 112 because it broadly claims a natural correlation not limited to the patentees' inventive assay method. That makes sense, for Congress could not have intended for the disclosure and enablement requirements to be met where no patentable "invention" exists in the first place. Pet. Br. 33 n.19. As in *Morse*, to decide the questions concededly presented here the Court must first confront whether Claim 13 seeks to patent a scientific principle.[5]

3. That issue was also passed upon by the District Court, which incorporated the bar against patenting scientific ideas into its claim construction.[6] And the Federal Circuit simply

[5] In *Diehr*, 450 U.S. at 189-191, the Court held that a claim that is anticipated or obvious under Sections 102 and 103 could still involve patentable subject matter. But the Court did not hold the converse, *i.e.*, that a non-patentable claim could satisfy Section 102 or Section 103. Nor, moreover, did the Court discuss Section 112, much less overrule *Morse*.

[6] *See* Pet. Br. 10; J.A. 131 ("[W]hat my ruling was is that you can't patent an idea. You have to patent an act or the test."); J.A.

ignored LabCorp's argument that not adhering to that critical limitation would render the claim invalid under *Diehr*. *See* Pet. Br. 14. But in any event, it has long been settled that "the question whether [an] invention is patentable or not[] is always open to the consideration of the court." *Slawson* v. *Grand St. R.R.*, 107 U.S. 649, 652 (1883); *see Richards* v. *Chase Elevator Co.*, 158 U.S. 299, 301, 302 (1895); *Hill* v. *Wooster*, 132 U.S. 693, 698 (1890); *Hendy* v. *Golden St. & Miners' Iron-Works*, 127 U.S. 370, 375 (1888); U.S. Cert. Br. 16 (Court has "inherent discretion" to consider issue).

This rule was not "abrogated" long ago. Resp. Br. 20. In fact, it was noted only last year that *Slawson* and its progeny "remain good law." *SmithKline Beecham Corp.* v. *Apotex Corp.*, 403 F.3d 1331, 1353 (Fed. Cir. 2005) (Gajarsa, J., concurring). Thus, in *SmithKline* the court decided subject matter patentability even though it had not been raised below. *See id.* at 1342 (rejecting argument on the merits). Respondents' assertion that the 1952 Patent Act overruled this rule *sub silentio* is further belied by the many other cases applying the rule after 1952.[7] The rationale for the rule remains valid: "[t]he centrality of patentable subject matter to the entire scope of patent law suggests that there are times when such inquiries are critical," particularly given the "significant

60 ("'Correlating' * * * must mean more than the simple existence of a relationship between a high level of homocysteine and a deficiency in cobalamin or folate.").

[7] *See id.* at 1353-54 (collecting cases); *Howes* v. *Great Lakes Press Corp.*, 679 F.2d 1023, 1028 (2d Cir. 1982) ("Section 101 deals with the subject matter of patents and, as such, it is 'always open to the consideration of the court.'") (citing *Slawson*); *Borden Co.* v. *Clearfield Cheese Co.*, 369 F.2d 96, 99-100 (3d Cir. 1966) ("It has been clear from an early date, that the court could dismiss a bill because the invention described in the patent was not patentable, even when no defense of invalidity was set up in the answer."); *Barkeij* v. *Lockheed Aircraft Corp.*, 210 F.2d 1, 2 (9th Cir. 1954) ("it is the duty of the court to dismiss a patent infringement suit whenever it affirmatively appears that the patent is invalid").

public policy interest in removing invalid patents from the public arena." *SmithKline*, 403 F.3d at 1353, 1354 (Gajarsa, J., concurring). Nothing in the pleading provisions of 35 U.S.C. § 282 speaks to, much less abrogates, this Court's settled inherent jurisdiction to consider this important legal issue. *See* S. Rep. No. 82-1979, at 9 (1952) (Section 282 did "not materially chang[e] the substance" of prior law); *cf. Salahuddin* v. *Jones*, 992 F.2d 447, 449 (2d Cir. 1993) (non-pleading of affirmative defense "does not deprive a court of the power to dismiss a claim on that ground"); 18 C. Wright, A. Miller, & E. Cooper, *Federal Practice and Procedure* § 4405, at 85-86 & n.8 (2002 & Supp. 2005) (same).[8]

Subject matter patentability is a pure "question of law" that is resolved by the court alone. *Mahn* v. *Harwood*, 112 U.S. 354, 358 (1884). Respondents cite *no* case where any part of that inquiry was held to be a jury issue, and this is not such a case. The invalidity of Claim 13 is apparent based solely on the Patent itself and the Federal Circuit's construction of it.[9]

[8] In any event, § 282 does not require specific pleading of § 101. Section 282(2) provides for pleading of invalidity on any ground "specified in part II of this title as a condition for patentability." 35 U.S.C. § 282(2). The only two grounds in part II of Title 35 specified as "Conditions for patentability" are Sections 102 and 103 – not Section 101. *See J.P. Stevens & Co.* v. *Lex Tex Ltd.*, 747 F.2d 1553, 1561 (Fed. Cir. 1984). And even if § 282(2) could be read, contrary to its text, to embrace other provisions not listed as "conditions for patentability," that would include § 112, which is also in part II. But § 282(3) provides *specifically* for pleading of invalidity under § 112. Section 282(2) thus could not require specific identification of Sections 101, 112 and every other ground in part II, because that would render redundant the part of § 282(3) that specifically identifies § 112. At most, § 282 provides for general notice of an invalidity defense, and for specific pleading of a § 112 defense (which was done here, *see* J.A. 66).

[9] Respondents' citation to *Unitherm Food Sys., Inc.* v. *Swift-Eckrich, Inc.*, 126 S. Ct. 980 (2006), is inapposite because subject matter patentability is not a jury issue for trial. *See Neely* v. *Martin K. Eby Const. Co.*, 386 U.S. 317, 327 (1967) ("issues of law" are "precisely the kind of issues that the losing defendant below may bring to the court of appeals without ever moving for a new trial"). In any event, unlike in *Unitherm*, LabCorp did renew its JMOL motion challenging the sufficiency of the evidence on factual issues that were for the jury. LabCorp argued there was no evidence doctors performed the necessary active step beyond mental recognition of the natural correlation, which the District Court had required to avoid invalidity. *See, e.g.*, LabCorp Renewed Mot. for JMOL 5 ("As interpreted by the Court, the second step of claim 13 must be 'a discrete step in a sequential process.' The Court has held that the second step must be an active step – a mental step is insufficient.") (R. 249). Respondents themselves understood LabCorp to have thereby presented subject matter patentability. *See* Plfs.' Resp. to Def's. Renewed Mot. for JMOL 15-17 (R. 263).

Whether that purely legal issue is considered in connection with the Section 112 arguments that are indisputably before the Court, or on its own, this Court can and should decide it.

II. CLAIM 13 IS INVALID.

It is not surprising that respondents expend so much effort urging the Court not to answer the question presented, because their argument on the merits is so feeble. A straightforward application of this Court's existing precedents compels the conclusion that Claim 13 is invalid.

A. Claim 13 Seeks To Patent A Scientific Principle.

1. LabCorp has shown that Claim 13 is invalid because it involves nothing of significance beyond the recited correlation. Pet. Br. 23-26. Respondents barely respond, asserting in a footnote that "the Court has never held that 'post-solution activity' is a prerequisite to patentability." Resp. Br. 33 n.15. That is not so. "[I]nsignificant post-solution activity will not transform an unpatentable principle into a patentable process." *Diehr*, 450 U.S. at 191-192. The same is necessarily true of the insignificant "pre-solution" activity of ascertaining an input for a correlation. *See Parker* v. *Flook*, 437 U.S. 584, 585 (1978) (invalidating patent despite "initial step which merely measures the present value of [a] variable").

Respondents do not contest that, if Claim 13 is valid, Einstein could have patented his famous equation by drafting a similar test-plus-correlate claim. *See* Pet. Br. 25. Even the PTO has made clear that "a claimed process which consists solely of the steps that one must follow to solve the mathematical representation of $E=mc^2$ is indistinguishable from the law of nature and would 'preempt' the law of nature. A patent cannot be granted on such a process."[10] The only thing that Claim 13 adds to the natural correlation is the empty requirement that the input be ascertained by *any* manner of test.

2. Respondents' principal defense is that the assay, or measuring, step of Claim 13 "[e]ntails" a physical transformation of matter because presently known methods of assaying for total homocysteine involve molecular disruptions. *See* Resp. Br. 33, 34. But what respondents trumpet as the saving virtue of Claim 13 – the generic measuring step – is in fact its worst vice. Claim 13 does not direct anyone how to physically transform anything. Instead, it covers *all* conceivable methods of assaying, whether previously known or yet to be invented. A generic direction to measure a manifestation of nature does not transform the phenomenon into patentable subject matter.

That some or all of these undescribed methods may entail physical transformation does not validate the attempt to patent a natural correlation. For example, the claim invalidated in *Morse* could only be implemented through some form of manufactured machine, but that did not save it. Likewise, it

[10] *Interim Guidelines for* [illegible]*ation of Patent Applications for Patent Subject Matter* [illegible], 1300 Off. Gaz. 142, Anx. V (2005). Thus, these Interim Guidelines do not support respondents. In any event, respondents wrongly assert that the Guidelines would be entitled to deference from this Court. *See* Resp. Br. 28. The PTO follows this Court, not vice versa. *See United States ex rel. Steinmetz* v. *Allen*, 192 U.S. 543, 560 (1904); *see also* 70 Fed. Reg. 75452 (Dec. 20, 2005) (extending comment period on Interim Guidelines to take account of Court's decision in this case).

may well be that all current methods of measuring energy entail physical transformation at the molecular level, but that would not validate a patent on Einstein's correlation between energy and mass. Claims that fully disclose and enable specific processes for physically transforming matter are usually patentable because they create something that did not previously exist in nature, and describe exactly what has been invented and what has not. For example, the Patent at issue *does* describe a transformative process – *the specific assay method recited in Claims 1-12* – and the validity of those claims is unchallenged. But *Claim 13* does not disclose, describe, or enable any such process.[11]

3. Respondents next argue that Claim 13 is valid merely if it produces a "useful, concrete, and tangible result." Resp. Br. 36-38. As support, respondents cite only Federal Circuit cases considering business methods and algorithms bearing no resemblance to Claim 13.[12] But this Court's precedents hold that the utility of a claimed application of a law of nature, while *necessary* to validity, is not *sufficient*. *See* Pet. Br. 30-31. The claims invalidated in *Morse*, *Funk Bros.*, *Benson* and *Flook* all produced useful, concrete, and tangible results, yet that did not suffice.

Indeed, the claim struck down in *Morse* involved one of the most useful concepts ever discovered – using electromagnetism to send information at a distance – which is the basis of all modern telecommunications.[13] And respondents' argu-

[11] The Guidelines upon which respondents mistakenly rely state that a claim is patentable if it "*provides* a transformation" of an article to a different state. Resp. Br. 14a (emphasis added). They do not, however, direct a finding of patentability for claims that nowhere recite or disclose a transformative process.

[12] The Federal Circuit originated the "useful, concrete, and tangible" phrase in the context of a machine claim employing an algorithm. *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994).

[13] The inclusion of the term "discovery" in the statutory definition of "invention," 35 U.S.C. § 100(a), does not help respondents.

ment is virtually identical to the unsuccessful argument of the dissenters in *Morse*. The dissent argued that Morse's overbroad claim should be valid because the concept was "not only 'a new and useful art,' * * * but a most wonderful and astonishing invention, requiring tenfold more ingenuity and patient experiment to perfect it, than the art of printing with types and press, as originally invented." 56 U.S. at 134 (Grier, J., dissenting). According to the dissent, "[i]f the result of this application be a new and useful art, and if the essence of his invention consists in compelling this hitherto useless element to record letters and words, at any distance and in many places at the same moment, how can it be said that the claim is for a principle or an abstraction?" *Id.* at 135.

The Court rejected that argument then, and should do so again now. Respondents' rule would eviscerate the prohibition against patenting laws of nature or natural phenomena, for virtually any such principle worth attempting to patent will have practical utility. *Diehr* did not adopt this radical view, nor did it overrule the more than a century of precedent to the contrary.[14] The saving feature of the claim at issue in *Diehr* was not simply its utility, but rather that it described a new method of physical transformation employed in an industrial process. *See* 450 U.S. at 184 ("That respondents' claims involve the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing

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Cf. Resp. Br. 18. As used in the statute, a discovery is a fortuitous invention. *See* Affymetrix Br. 24-25 n.19; Amer. Heart Ass'n Br. 9-10. Laws of nature "are not the kind of 'discoveries' that the statute was enacted to protect." *Flook*, 437 U.S at 593.

[14] Nor did *Diehr* "reject[ ]" or "supersede[ ]" *Flook* in any other material respect. Resp. Br. 37. *Diehr* clarified that, in determining validity, "claims must be considered as a whole." 450 U.S. at 188. Here, when Claim 13 is considered "as a whole," it involves nothing of significance beyond the natural correlation it recites. Unlike in *Diehr*, this is not an instance where "'the whole in some way exceed[s] the sum of its parts.'" *Id.* at 193 n.15 (citation omitted).

cannot be disputed."). Claim 13 describes no such method. Instead, as construed by the Federal Circuit it involves merely the reflexive recognition of a natural correlation accompanied only by the token step of ascertaining the input for that correlation. More is required for a valid patent.

4. Because Claim 13 clearly lacks the criteria laid out in *Morse* and its progeny – it describes no process of physical transformation and involves nothing of significance beyond the natural phenomenon it recites – there is no need to also examine whether Claim 13 substantially preempts practical applications of the correlation. *See* Pet. Br. 28-29. Such preemption would invalidate even a claim that meets other criteria for a patentable invention; but not even respondents contend that a claim is patentable as long as it passes the preemption test. To the contrary, this Court has consistently held that a patent on a law of nature is invalid "regardless of whether the patent is intended to cover all uses of [the law] or only limited uses." *Diehr*, 450 U.S. at 192 n.14.

But the vast breadth of Claim 13 creates a prohibited preemptive effect, even more so than the claim invalidated in *Benson*. Claim 13, as construed below, covers *every* homocysteine test by every method – whether prior art or yet-to-be invented – and every doctor who even looks at an ordered test result necessarily infringes. Respondents' own listing of hypothetical instances where the correlation allegedly could be used without infringing in fact shows the claim's prohibitive sweep. Respondents postulate that doctors might administer vitamins to people suspected of having elevated homocysteine, *without* ever testing to confirm that fact. *See* Resp. Br. 41-42. Thus, a doctor can employ the correlation between elevated homocysteine and vitamin deficiencies without infringing only by avoiding inquiry as to whether a patient in fact has elevated homocysteine in the first place. That doctors would have to go to such absurd and dangerous

lengths to avoid Claim 13 shows its impermissible reach.[15] Moreover, most of respondents' hypotheticals depend on prior research establishing that people in a specific population are likely to have elevated homocysteine, but that research itself requires infringing conduct.

The Solicitor General admits that a claim the PTO itself granted is likely invalid because "claim 13 appears to cover all substantial practical applications of the natural phenomenon." U.S. Br. 24. The Solicitor General is correct. But his proposed solution – a remand to determine possible current or future uses of the correlation not encompassed by Claim 13 – is unnecessary, unworkable, and contrary to law. The Court in *Benson* did not require an evidentiary hearing to determine that digital computers were the only substantial practical application of a binary conversion algorithm, *see* 409 U.S. at 71-72, and LabCorp knows of no case endorsing such a rule. Nor would that procedure make sense. Validity rules must be straightforward enough for patent examiners to apply easily and quickly. The PTO cannot seriously advocate that before denying a patent its own examiners must (1) determine all conceivable practical uses of a scientific principle, including divining uses not yet discovered; (2) ascertain the ratio of infringing to non-infringing uses; and (3) decide whether the ratio is sufficiently substantial.[16]

Claim 13 is automatically infringed whenever a doctor looks at a test result and thinks about a scientific principle, and this resulted in an injunction against *all* homocysteine

[15] The Patent itself makes clear that it is dangerous to administer a vitamin – either folate or cobalamin – without first diagnosing which vitamin is deficient in a patient. *See* Pet. Br. 8.

[16] The Solicitor General – but not respondents – suggests that Claim 13 might be valid because it only covers assays of body fluids. U.S. Br. 25. But LabCorp was enjoined from conducting *any* homocysteine tests. In any event, one cannot patent a correlation simply by limiting it to one input; Einstein, for example, could not have patented his equation by limiting it to one kind of matter.

testing by any method. No more is required to determine that the claim has an impermissible preemptive scope.

B. Claim 13 Violates The Disclosure And Enablement Requirements Of The Patent Laws.

Claim 13 also contravenes the disclosure and enablement requirements of Section 112 for largely the same reasons that it fails the subject matter patentability test. *See* Pet. Br. 32-42; *SmithKline*, 403 F.3d at 1361 ("[T]he inevitable failure of the patent to provide public notice * * * stems from the inherently unpatentable nature of the claimed subject matter.") (Gajarsa, J., concurring). Claim 13 is not definite because it does not define any specific "assay," or what "correlating" means beyond recognition of a scientific principle. And it is neither sufficiently enabled nor described because the claim and its specification fail to identify "with clearness and precision," *Tyler* v. *City of Boston*, 74 U.S. (7 Wall.) 327, 330 (1868), any invention – beyond the scientific relationship between elevated homocysteine and vitamin deficiencies.

As LabCorp explained in its opening brief, this Court's landmark ruling in *Morse* provides the rule of decision here. In addition to patenting a concededly valid specific device (the telegraph) for printing characters at a distance, Samuel Morse sought to patent more broadly the use of electromagnetism for that purpose. *See* 56 U.S. at 112. As noted (*supra* at 5-6), the Court invalidated that claim under what is now Section 112. The Court explained that an inventor must "specif[y] the means he uses in a manner so full and exact, that any one skilled in the science * * * can, by using the means he specifies * * * produce precisely the result he describes. And if this cannot be done by the means he describes, the patent is void." *Id.* at 119. Morse's broad claim was held void under that rule because "he claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent." *Id.* at 113.

Allowing Morse to claim a scientific principle, rather than the specific device he invented, would have "shut[ ] the door against inventions of other persons," including devices "less complicated – less liable to get out of order – less expensive in construction, and in * * * operation." *Id.* at 113. Under this claim, "there was no necessity for any specification, further than to say that he had discovered that, by using the motive power of electro-magnetism, he could print intelligible characters at any distance" but "no patent could have issued on such a specification." *Id.* at 119. The claim could "derive no aid from the specification filed. It is outside of it, and the patentee claims beyond it." *Id.* at 119-120.[17]

Morse is indistinguishable from this case in every material respect. Claim 8 of Morse's patent and Claim 13 of this Patent both violate Section 112 because they reach well beyond the scope of the patentees' actual inventions to claim more generally any process or device, whether in existence or yet to be developed, that allows one to use a discovered natural phenomenon. Morse sought to monopolize telecommunications devices he did not disclose or enable, and the patentees here have monopolized assay methods they did not disclose or enable. Even the justifications posited for the patents are eerily similar. Morse stated that because the "essence" of his invention was the use of electromagnetism to print characters at a distance, he did not "propose to limit [him]self to the specific machinery or parts of machinery described" in the specification. 56 U.S. at 112. Here, the patentees stated to the PTO that the scientific correlation was the "heart" of their invention, and that because they were the first to detect vitamin deficiencies through a total homocysteine test, they were "entitled to a claim of equivalent scope,

[17] This was an application of the settled rule under Section 112 – which respondents ignore – that a claim may cover a process "'but never [its] function or result * * * nor the scientific explanation of [its] operation.'" *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) (citation omitted). *See* Pet. Br. 38-39.

not limited to any particular process steps or methods." J.A. 278, 281. Indeed, the precise evil *Morse* sought to prevent has come to pass in this case: LabCorp has been enjoined from using the new Abbott assay method, even though it is far more efficient than the patentees' own invention.[18]

Respondents' brief contains but a single citation to *Morse*, in a footnote. And what they do say is demonstrably wrong. Respondents contend that *Morse* is distinguishable because "[w]hereas Morse claimed all uses of a natural phenomenon, the '658 patent claims just one." Resp. Br. 39-40 n.19. That mischaracterizes both *Morse*'s patent and this one. Claim 8 of Morse's patent purported to claim "just one" application of a natural phenomenon: namely, "'the use of * * * electromagnetism, however developed, *for marking or printing intelligible characters, signs, or letters, at any distances* * * *.'" *Morse*, 56 U.S. at 112 (quoting patent) (emphasis added). And the Federal Circuit in fact held that Claim 13 is *not* limited to a particular use, but applies whenever a doctor looks at a test result. Pet. App. 18a.[19]

[18] The Solicitor General asserts that Claim 13's "breadth" likely renders it invalid for anticipation under 35 U.S.C. § 102. U.S. Br. 28-30 & n.8. He is right that the claim's overbreadth renders it invalid, but as in *Morse*, the invalidity is under Section 112. Claim 13's vice is not simply that it sweeps in prior art assays, but that it covers *all* conceivable assays including those – like the Abbott method – not even invented when the Patent application was filed. Similarly, the claim at issue in *Morse* contravened what is now Section 112 even though the claim did not read on any prior art given that Morse was the first inventor of the telegraph.

[19] Respondents argue (Br. 40 n.19) that the telephone patent in *Dolbear* v. *American Bell Tel. Co.*, 126 U.S. 1 (1888), is "the more apt analogy." The claim at issue there, however, was "not for the use of a current of electricity in its natural state * * * but for putting a continuous current, in a closed circuit, into a certain specified condition, suited to the transmission of vocal and other sounds, and using it in that condition for that purpose." *Id.* at 534. The claim was not "one for the use of electricity distinct from the particular

Respondents otherwise merely parrot the Federal Circuit's reasoning, contending that Claim 13 is sufficiently disclosed and enabled because the specification "explains that '[i]t has been discovered that elevated levels of homocysteine in body tissue correlate with decreased levels of cobalamin and/or folic acid in said body tissue.'" Resp. Br. 16 (quoting S.A. 12). But that is simply a recitation of the natural correlation itself, and under *Morse* such a description will not satisfy Section 112. In *Morse*, it was "impossible to misunderstand the extent of [the] claim," 56 U.S. at 112, but that fact did not save it because neither the claim nor the specification described or enabled an invention beyond the recited natural phenomenon. So too here, nothing in Claim 13 or its specification describes or enables either a specific assay method or specific method of correlating beyond the mere recognition of a natural phenomenon. Claim 13 is therefore overbroad and invalid under Section 112.

Respondents also argue that the specification "describe[s] in detail" how the patentees "established the mutual and reciprocal relationship between total homocysteine and vitamin deficiency," Resp. Br. 15 – that is, how they conducted a clinical study to discover the natural correlation. But that description, however detailed, does not render Claim 13 definite, enabled or sufficiently described. Claim 13 does not inform practitioners how to conduct a clinical study; rather, it merely informs them that the natural correlation exists. Likewise, it is immaterial that the "specification describes in great detail the manner in which to conduct assays." Resp. Br. 17; *see also* U.S. Br. 10 (specification "includes two detailed examples that describe how the applicants measured homocysteine using different assay methods"). One new method of assaying for homocysteine – the patented method in Claims 1 through 12 – is disclosed and enabled. But

process with which it is connected in his patent." *Id.* at 535. In contrast, Claim 13, like Morse's claim, is for a scientific principle divorced from any inventive process or device. *See Benson*, 409 U.S. at 68 (distinguishing *Dolbear* from *Morse* in this way).

Claim 13 claims no particular assay method at all. It claims instead a vague and generic "assay" for homocysteine, sweeping within its scope *every* homocysteine test, whether in the prior art or yet to be invented. As in *Morse*, it is the Patent's utter lack of any further description that renders Claim 13 invalid under Section 112.[20]

III. UPHOLDING CLAIM 13 WOULD STIFLE RATHER THAN PROMOTE INNOVATION.

Respondents barely address, much less dispel, the dangerous consequences of allowing Claim 13 to stand.[21] Instead, they seek to deflect attention from the fatal defects in their own patent by raising the specter that invalidating Claim 13 would call into question "thousands" of other unnamed patents, including in such disparate areas as business methods, genes, and software. Resp. Br. 44 & n.23. Such fear-mongering is unfounded. This case involves a specific patent claim that is invalid under this Court's existing precedents. LabCorp does not ask the Court to overrule *Diehr* or any other case. Indeed, it is telling that the only party asking for the Court to overrule its precedents is one of *respondents'* amici. *See* Franklin Pierce Br. at 21-26.

A ruling invalidating Claim 13 would not directly bear on disparate patents for business methods, genes, or computer software. Each of those patents, like every other patent, would have to be examined on its own merits according to its

[20] Respondents wrongly suggest that the Section 112 inquiry in this case is factual in nature. *See* Resp. Br. 17. Although the determination sometimes entails factual issues, "[t]he ultimate test of patent validity is one of law." *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 280 (1976). As in *Morse*, no disputed factual issues need to be resolved to determine that Claim 13 is overbroad and invalid.

[21] Respondents state that they have abstained so far from suing doctors. But the doctors *are* the infringers under their theory, and this action against LabCorp has had the desired result of monopolizing a critical medical test. Moreover, if Claim 13 is allowed, patentees of other natural correlations would be free to sue doctors.

own claims and specification. The deficiencies of *this* patent claim are clear-cut. Claim 13 involves nothing more than reflexive mental recognition of a natural correlation, preceded by the token activity of ascertaining the input for the correlation. Invalidating that rogue claim would not require invalidation of other types of claims, such as those that fully disclose and enable processes of physical transformation. Nor would such a ruling even affect other kinds of medical diagnostic patents. To the contrary, the very patent at issue in this case claims a diagnostic procedure whose validity has not been challenged: a novel method for diagnosing elevated homocysteine via the specific assay method set forth in Claims 1-12. Thus, as numerous amici have made clear, the Court need not and should not address or opine upon patent claims that are not before the Court in this case.

But if there are in fact other patents that follow the same rudimentary "test plus correlate" formulation of Claim 13, that is even more reason to ensure that the claim does not stand. Such patents on medical or other natural correlations improperly permit parties to monopolize concepts and tests they did not invent and to stifle the free flow of medical and scientific information. *See* Pet. Br. 43-47. The patent laws do not allow that result, and the Court should not sanction it.

CONCLUSION

For the foregoing reasons, and those in the opening brief, the judgment should be reversed.

Respectfully submitted,

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